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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,534	09/04/2001	Marco A. Coccia	P 0280624	9135
909	7590	10/02/2003	EXAMINER	
PILLSBURY WINTHROP, LLP			GAMBEL, PHILLIP	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			1644	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/856,534

Applicant(s)

COCCIA, MARCO A.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

One of the special technical features of the instant application is a chimeric protein comprising a heavy chain variable region binding domain and a binding portion of an immunostimulatory ligand to cause or modulate an immune response (e.g. see Group II below). Whitlow et al. (U.S. Patent No. 5,767,260 teaches antigen-binding fusion proteins, encompassing various immunoeffector molecules, including cytokines (e.g. see column 9, lines 48-67) (see Summary of the Invention and Detailed Description of the Invention), as well as Genetic Constructs and Gene Expression thereof (columns 16-17) (as it reads on Group I below). With respect to CD40L, Grabstein et al. (U.S. Patent No. 5,747,024) teach the use of CD40L as a vaccine adjuvant (See entire document, including column 4, paragraph 1). In addition, Mond et al. (U.S. Patent No. 5,932,427) teach the use of CD40L as an adjuvant in vaccine constructs (see entire document, including the first paragraph of the Detailed Description of the Invention in column 8). One of ordinary skill in the art would have been motivated to construct and employ the immunoconjugates, including recombinant forms thereof, as taught by Whitlow et al. to modulate the immune response. In addition, given the stimulatory properties of CD40L, as taught by Grabstein et al. and Mond et al., one of ordinary skill in the art would have been motivated to modify the constructs taught by Whitlow with CD40L to increase immune responses to antigens of interest at the time the invention was made. Therefore the inventions of either Group I or 2 has not been found to have a special technical feature that defines a contribution over the prior art.

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

I. Claims 1-8, 20-22, drawn to nucleic acid molecules comprising nucleic acids that encode a heavy chain variable region binding domain and a binding portion of an immunostimulatory ligand, vectors and host cells comprising said nucleic acids, kits comprising and methods of expressing the proteins encoded by said nucleic acids.

II. Claims 9-18, drawn to chimeric protein comprising a heavy chain variable region binding domain and a binding portion of an immunostimulatory ligand and kits comprising said chimeric protein

III. Claim 23, drawn to methods of enhancing disease antigen-specific antibody responses by administering the chimeric protein comprising a heavy chain variable region binding domain and a binding portion of an immunostimulatory ligand.

IV. Claim 24, drawn to methods of treating a disease by administering a chimeric protein comprising a heavy chain variable region binding domain and a binding portion of an immunostimulatory ligand.

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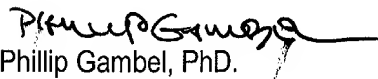
Applicant is invited to distinguish the recitation of claims 23 and 24. It is not readily apparent whether these claims are directed to the same or nearly the same methods or these claims comprise different ingredients, method steps and endpoints. If it is the former, then claims 23-24 would be considered in the same Group. If the later, then claims 23 and 24 would retain their status as different Groups (e.g Group III and Group IV), as indicated above.

2. This application contain claims directed to more than one species of the generic Inventions I-IV.
In addition to electing a Group from Inventions I-IV, applicant must elect a species disease specificity from:
A) viral or
B) tumor.

These species are distinct because the targets address differ structures and in turn address different pathological conditions which differ in etiologies and therapeutic endpoints.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306


Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 29, 2003